REMARKS

PRELIMINARY REMARKS

Original Claims 1-82 have been made subject to a six-way restriction requirement. The Restriction Requirement separates the original claims into Groups:

I. Claims (1 and) 3-35 for treatment methods involving administering an antibody-based molecule as defined;

II. Claims (1 and) 2-37 for treatment methods involving administering a nucleic acid encoding the antibody-based molecule;

III. Claims 38-71, 76 and 82 for the antibody-based molecule;

IV. Claims 38-76 and 82 for a nucleic acid encoding the antibody-based molecule, vectors and cell lines comprising the nucleic acid, cell lines comprising the vector, pharmaceutical compositions comprising the nucleic acid, and kits containing the nucleic acid;

V. Claim 77 for methods for preparing the antibody-based molecule using a vector comprising a nucleic acid encoding the antibody-based molecule; and

VI. Claims 78-81 for vaccine compositions comprising the antibody-based molecule.

However, in regard to Group VI, Applicants respectfully point out that original Claims 78-81 do not recite that the vaccine compositions comprise an antibody-based molecule, but a nucleic acid according to original Claim 38. As a result, Applicants believe that the subject matter of Group VI properly belongs within Group IV, as all claims share the operative feature of being or comprising nucleic acid according to original Claim 38.

Also in light of this mistaken characterization of the subject matter of Group VI, Applicants believe that the comments presented in Item 4 of the Office Action are not clear as to why the subject matter of original Claims 78-81 is considered distinct from that of the claims of Group IV. In particular, Applicants point out that the reason why the vaccine compositions of original Claim 78-81 are "able to trigger both a T-cell- and B-cell-immune response" is because, upon transformation and expression of the recited nucleic acid, a recombinant antibody-based molecule according to original Claim 38 is

produced. In other words, the "able to trigger" element of these claims relies upon production of the encoded protein that is then directly involved in the recited immune response. See, e.g., Figures 21-24 and their brief description at paragraphs [0031] to [0034] at pages 11-13, as well as Examples 4 to 6 at pages 33-35, of the Specification. Thus, these claims do not indicate that the nucleic acid is itself either an immunomolecule that directly effects, or an antigenic molecule that directly elicits, the recited immune response.

This means that the mode of operation, the function, and the effect of the vaccine composition of original Claims 78-81 is a result of its containing the very same nucleic acid sequence as is defined by original Claim 38, i.e. the nucleic acid that encodes the antibody-based molecule recited therein: the claimed vaccine composition must encode this antibody-based molecule in order for the composition to have the recited ability to trigger the immune response. Likewise, the structure of that polypeptide-molecule-encoding nucleic acid sequence has the same design in either the vaccine composition claims or the polynucleotide claims, and the nucleic acid of original Claim 38 is clearly capable of use in the recited vaccine compositions. For these reasons, and because the subject matter of Claim 78 is expressly dependent upon that of Claim 38, Applicants believe that the subject matter of the claims is not mutually exclusive.

Moreover, as described in the Application, "vaccine compositions" according to claims of Group VI, which comprise the recited nucleic acid, can be construed as one specific subgenus of "pharmaceutical compositions" comprising the recited nucleic acid, such as pharmaceutical compositions defined by claims of Group IV. Additionally, that the subject matter of the Group IV and Group VI claims is so closely related or does

overlap to such an extent is further highlighted by the manner in which these claims have now been rewritten such that they are all clearly directed to embodiments that are or comprise the nucleic acid according to original Claim 38. See new Claims 83-130.

Therefore, for all of these reasons, Applicants believe that the subject matter of Group VI (original Claims 78-81, now new Claims 124-130) properly belongs within Group IV (original Claims 38-76 and 82, now new Claims 83-123), as all claims share the operative feature of being or comprising nucleic acid according to original Claim 38. In light of these remarks, Applicants respectfully request rejoinder of Groups IV and VI.

REMARKS IN CHIEF

Of original Claims 1-82: Claims 1-37 and 77 have now been withdrawn; and Claims 38-76 and 78-82 have now been cancelled and rewritten as new Claims 83-130. Thus, original Claims 1-37 (withdrawn) and 77 (withdrawn), and new Claims 83-130 are now pending in the Application. New Claims 83-123 comprise subject matter of original Claims 38-76 and 82, i.e. restriction Group IV; and new Claims 124-130 comprise subject matter of original Claims 78-81, i.e. restriction Group VI. These changes are summarized in the following table.

Original Claims	New Claims (or Status)	Elected Group
1-37	(withdrawn)	(none)
38-57	83-102	IV
(none)	103	IV
58-72	104-118	IV
73	119	IV
74, 75	120	IV
76	121, 122	IV
77	(withdrawn)	(none)
78-80	124-126	VI
(none)	127, 129	VI
81	128, 130	VI
82	123	IV

The basis for new Claims 83-130 is as follows.

New Claims 83-102 are rewritten versions of original Claims 38-57, respectively; support for these new Claims is found therein. Original Claim 38, directed to an antibody-based molecule or nucleic acid encoding it, was rewritten as new Claim 83, directed to nucleic acid encoding the antibody-based molecule. Original Claims 39-57, directed to specific features of various embodiments of the antibody-based molecule, were rewritten as new Claims 84-102, directed to nucleic acid encoding an antibody-based molecule having those features.

In new Claim 94, an obvious typographical error has also now been corrected by changing "flaggelin" to "flagellin." The same change is also made by amendment in now withdrawn Claim 13. In new Claim 96, a minor syntax error has now been corrected by rewriting, in singular form, the terms "toll-like receptors" and "chemokine receptors;" in parallel with this correction, the recitation of "chemokine receptors" in new Claim 98 has also now been made singular. Support for these changes is found, e.g., in original Claims 51 and 53, and at paragraphs [0091]-[0092], at page 37, of the Specification. These same changes are also made by amendment in now withdrawn Claims 15 and 17, respectively. Now withdrawn Claim 15 is also amended to correct an obvious error by changing "HLA-DP" to "HLA" in order to provide the proper antecedent basis for "HLA" in dependent Claim 16, and to eliminate any potential redundancy with "HLA-DP" in Claim 16. Support for this amendment to Claim 15 is found, e.g., in original Claims 51 and 52, and in paragraphs [0006], at page 3, and [0054], at page 23, of the Specification.

New Claim 103 is directed to the nucleic acid of new Claim 83, wherein at least one of the antigenic units of the antibody-based molecule is derived from an infectious agent. Support for new Claim 103 is found, e.g., in paragraph [0040], page 16, of the Specification, and original Claim 78.

New Claims 104-118 are rewritten versions of original Claims 58-72, respectively; support for these new Claims is found therein. In light of the fact that new Claim 83 is directed to nucleic acid encoding the antibody-based molecule, new Claims 104-118, which depend from new Claim 83, were prepared by rewriting original Claims 58-72, directed to specific features of various embodiments of the antibody-based molecule of original Claim 38, as these new claims that are directed to nucleic acid encoding an antibody-based molecule having those features. New Claims 104 and 106 (q.v. original Claims 58 and 60), which are directed to embodiments in which antigenic unit(s) of the antibody-based molecule are derived from a bacterium or virus, respectively, also recite further embodiments by multiple dependency to new Claim 103, discussed above.

New Claim 119 is a rewritten version of original Claim 73; support for this new Claim is found therein. Whereas original Claim 73 was directed to embodiments in which the nucleic acid of original Claim 38 is comprised by a vector, new Claim 119 is directed to a vector comprising the nucleic acid.

New Claim 120 is a rewritten version of original Claims 74 and 75, the subject matter of these two original Claims being combined into new Claim 120; support for this new Claim is found therein. Whereas original Claims 74 and 75 were directed to embodiments in which the nucleic acid of original Claim 38, or a vector comprising that

nucleic acid, is comprised by a cell line, new Claim 120 is directed to a cell line comprising the nucleic acid or the vector that comprises that nucleic acid.

New Claims 121 and 122 are rewritten versions of original Claim 76. Whereas original Claim 76 was directed to a pharmaceutical composition comprising a recombinant molecule of original Claim 38: new Claim 121 is directed to a pharmaceutical composition comprising the nucleic acid of new Claim 83 (i.e. original Claim 38), and includes further embodiments in which the nucleic acid thereof is located within a vector; and new Claim 122 is directed to the pharmaceutical composition wherein the nucleic acid or vector is located within a cell. Support for new Claims 121 and 122 is found, e.g., in paragraphs [0044]-[0045], at pages 18-19 of the Specification, and in original Claim 76.

New Claim 123 is a rewritten version of original Claim 82; support for this new Claim is found therein. Although both of these versions of the claim are directed to kits for the preparation of an antibody-based molecule encoded by the nucleic acid according to original Claim 38 (new Claim 83), further language has been added to new Claim 123 in order to expressly recite that the kit contains the nucleic acid. Additional support for new Claim 123 is found, e.g., in paragraph [0044], at page 18, of the Specification.

New Claims 124-126 are rewritten versions of original Claims 78-80, respectively; support for these new Claims is found therein. New Claim 126 also recites further embodiments by multiple dependency to new Claim 125, which specifies embodiments in which the vaccine compositions also comprises a pharmaceutically

acceptable carrier. Additional support for new Claim 126 is found, e.g., in paragraph [0044], at page 18, of the Specification.

New Claims 128 and 130 are rewritten versions of original Claim 81; support for these new Claims is found therein. Whereas original Claim 81 defined embodiments of the vaccine composition in which its infectious disease target is AIDS or tuberculosis, new Claim 128 defines embodiments against tuberculosis and new Claim 130 defines embodiments against AIDS.

New Claims 127 and 129 are each directed to embodiments of the vaccine composition of new Claim 124 (vaccine composition) and new Claim 125 (embodiments comprising a pharmaceutically acceptable carrier), wherein the infectious disease target is a "bacterial infection" (Claim 127) or a "viral infection" (Claim 129). These claims are intermediate between the broader Claims 124 and 125, and the respective narrower claims: Claim 128, which depends from Claim 127; and Claim 130, which depends from Claim 129. Support for these new intermediate Claims 127 and 129 is found, e.g., in original Claim 78 (reciting "infectious disease"), and at paragraph [0040], page 16, of the Specification (reciting "infectious agents"). Applicants believe that these descriptions, in the Application as filed, of the genera of "infectious diseases" and "infectious agents," and the various descriptions and original claim recitations of "bacterial" antigens as types of polypeptide sequences useful for parts of the recombinant antibody-based molecule and the descriptions of various viruses (e.g., HIV and EB) for parallel purposes, provide support for the intermediate categories of bacterial infectious disease and viral infectious diseases, as recited in new Claims 127 and 129.

The various items raised in the Office Action are addressed below in the order in which they were presented.

Items 1 to 12: Election of Claims

Applicants elect rejoined Group IV and VI. However, in the event that Group VI is not rejoined with Group IV, Applicants elect Group IV with traverse. As discussed above, Applicants believe that the claims of Group VI rightly belong within Group IV and respectfully request rejoinder of these two groups. The claims that are involved in the provisional election of Group IV include new Claims 83-123; and the claims that are involved in the election of rejoined Group IV and VI are new Claims 83-130. Applicants also expressly reserve the right to rejoin unelected/withdrawn process claims in the present Application, upon a finding of allowability of corresponding product claims.

Item 13: Election of Targeting Units

13A. Election of Species. The Office Action indicates that, for purposes of initiating substantive examination, Applicants must elect one species of targeting unit from among (A) scFv, (B) ligand, and (C) bacterial antigen. Applicants respectfully request that they be permitted to elect targeting units that have the ability to target antigen-presented cells (APC). However, in the event this is not permitted, Applicants provisionally elect species (B) ligand. The claims that are involved in the provisional election of targeting unit species (B) ligand include new Claim 83 and its dependent claims, particularly new Claims 88-92.

13B.-13C. Election of Subspecies. The Office Action indicates that, for purposes of initiating substantive examination, Applicants must elect one subspecies of the elected targeting unit species that, in light of the provisional election of species (B) ligand, is to be elected from among (A) CD40 ligand and (B) chemokine. In keeping with the provisional election of species (B) ligand, Applicants likewise provisionally elect subspecies (B) chemokine. The claims that are involved in the provisional election of targeting unit subspecies (B) chemokine include new Claim 83 and its dependent claims, particularly new Claims 89-92, 96, and 98.

13D. Election of Sub-Subspecies. The Office Action indicates that, for purposes of initiating substantive examination, Applicants must elect one sub-subspecies of the elected targeting unit subspecies that, in light of the provisional election of subspecies (B) chemokine, is to be elected from among (A) RANTES and (B) MIP-1α. In keeping with the provisional election of subspecies (B) chemokine, Applicants likewise provisionally elect sub-subspecies (B) MIP-1α. The claims that are involved in the provisional election of targeting unit sub-subspecies (B) MIP-1α include new Claim 83 and its dependent claims, particularly new Claims 91-92.

Item 14: Election of Antigenic Units

The Office Action indicates that, for purposes of initiating substantive examination, Applicants must elect one species of antigenic unit from among (A) antigenic scFv, (B) telomerase, (C) bacterium, and (D) virus. Applicants elect species (A) antigenic scFv. The claims that are involved in the election of targeting unit species (A) antigenic scFv include new Claim 83 and its dependent claims, particularly new Claims 99-100.

Item 15: Election of Vaccine Composition

The Office Action indicates that, for purposes of initiating substantive examination, Applicants must elect one species of vaccine composition from among: (A) cancer, i.e. anti-cancer vaccine compositions; and (B) infectious disease, i.e. anti-infectious disease vaccine compositions. Applicants elect species (A) cancer. The claims that are involved in the election of targeting unit species (A) cancer include new Claim 83 and its dependent claims, particularly new Claims 124-126.

Item 16: Identification of Claims Relating to the Elected Species

Applicants have identified which ones of the presently pending claims relate to which elections in each of the above-stated elections, in light of the Claim amendments and additions presented herein.

Applicants note that the above elections are made for purposes of initiating substantive examination and will not limit the claims; however, if no generic claim is ultimately held to be allowable, then it is possible that only certain narrower versions of the claims would be held allowable. Applicants also note that withdrawn Claims 1-37 and 77, as well as the withdrawn subject matter of the Group III Claims 38-71, 76, and 82, are reserved for the purpose of future use in the present Application and/or may be made the subject of one or more Divisional applications.

CONCLUSION

It is believed that a full and complete response has been made to all of the issues raised in the outstanding Office Action. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: 9-11-06

By: Mark S. Scott

Mark S. Scott, Reg. No. 43,101

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600

RMS:MSS:mhe